

**510(k) SUMMARY**

MAY 19 2011

"Special 510 (K): Device Modification" Premarket Notification: **Zenius™ Spinal System**

**1. Submitter/Sponsor:**

Medyssey Co. Ltd.

Patrick D. Moore, Official US Correspondent

722-3, 4F. Science Tower, Jihaeng-dong, Dongducheon-city, Gyeonggi-do, Korea

**Contact person:**

Patrick D. Moore

Official US Correspondent

Medyssey Co. Ltd.

6170 South 380 West, Suite 200. Murray, Utah. 84107

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**Date Prepared:**

January 27, 2011

**2. Device Name:**

Classification Name: Pedicle Screw Spinal System

Common/Generic Name: Pedicle Screw Spinal System

Trade Name: Medyssey Co., Ltd. *Zenius™* Spinal System**3. Device Classification(s):**

- Pedicle Screw Spinal System – MNI, MNH - 21 CFR § 888.3070

**4. Predicate Device:**Medyssey Co., Ltd., *Zenius™* Spinal System (K093104)Medyssey Co., Ltd., *Zenius™* Spinal System (K103272)**5. Device Description:**

The *Zenius™* Spinal System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a transverse (cross) linking mechanism. The *Zenius™* Spinal System implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the *Zenius™* Spinal System implants.

**6. Intended Use:**The Medyssey Co. Ltd., *Zenius™* Spinal System, a posterior spinal fixation

device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

**7. Comparison with predicate device:** The Modified *Zenius*<sup>TM</sup> Spinal System is substantially equivalent to the currently marketed *Zenius*<sup>TM</sup> Spinal System. When considered for Posterior applications, both the Modified *Zenius*<sup>TM</sup> Spinal System and the *Zenius*<sup>TM</sup> Spinal System worst case constructs consist of the same universal housing containing the same pre-assembled pedicle screw and set screw. Both systems use the same vertical rods which are both placed into the housing. The same set screws are subsequently tightened onto the rod, providing a completed implant assembly.

The principles of operation for the subject *Zenius*<sup>TM</sup> Spinal System device, and the cited predicate technologies are same. That is, each of these products employs the same indications for use, contraindications for use, warnings and precautions within labeling. The principles of operation of the subject device are directly equivalent to those of the cited predicates cleared by the Agency and currently being marketed.

The design and development process of the manufacturer of subject system and Predicate system conforms to 21 CFR part 820, Quality System Regulation. The subject and predicate device was evaluated/tested per established requirements.

The subject/predicate device underwent mechanical testing included Static Compression Bending; Static Tension Bending; and Static Torsional Testing. All testing performed per ASTM F 1717-04. However, the purpose of the submission is the clearance of the redesign of the custom sterilization trays, therefore the new modified custom dedicated sterilization tray(s) (are not worst case) and therefore not subject to ASTM F 1717-04 additional testing. However, a new Sterilization Validation according to AAMI ST77 and AAMI ST79 guidelines to achieve a degree of Sterility Assurance Level (SAL) equal to at least  $1 \times 10^{-6}$ ; is required, and was satisfactorily preformed on the re-designed sterilization trays; the validation summary is presented within the body of this submission. Clinical tests: No clinical tests conducted on either the subject system nor the predicate system.

**Conclusion:** The subject device was evaluated against the predicate device for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Medyssey Co., Ltd.  
% Mr. Patrick D. Moore  
6170 South 380 West, Suite 200  
Murray, Utah 84107

MAY 19 2011

Re: K110283

Trade/Device Name: Zenius™ Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH  
Dated: April 25, 2011  
Received: April 27, 2011

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

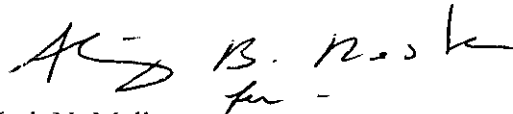
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**"Special 510(k): Device Modification" Number (if known):**

**Device Name:** Medyssey Co., Ltd. *Zenius<sup>TM</sup>* Spinal System

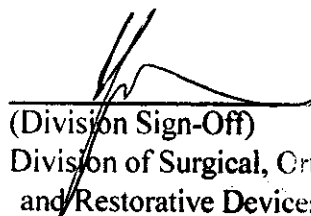
**Indications for Use:** The Medyssey Co. Ltd., *Zenius<sup>TM</sup>* Spinal System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

Prescription Use   X   OR Over-the-Counter Use            (Per 21 CFR 801.109)  
(Optional Format 1-2-96)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K110283